Amendments to the Claims

This listing of claims will replace all prior versions and listings of claims in the application.

Claims 1 to 357 (canceled).

358. (currently amended) A method for delivering a polypeptide into a vertebrate, comprising administering into a tissue or cavity of said vertebrate a composition comprising:

(a) about 1 ng to about 30 mg of a polynucleotide in aqueous solution ~~which operably encodes~~ , wherein the polynucleotide expresses a polypeptide upon delivery to vertebrate cells *in vivo*;

(b) a salt M-X dissolved in said aqueous solution at a molar concentration ranging from about 50 mM to about 250 mM, and reaction, association, and dissociation products thereof, wherein M is a cation selected from the group consisting of sodium and potassium, wherein X is an anion selected from the group consisting of phosphate, acetate, bicarbonate, sulfate, and pyruvate; and

(c) an auxiliary agent selected from the group consisting of a poloxamer and a reverse poloxamer;

wherein said aqueous solution contains chloride ion at a molar concentration ranging from 0 mM to about 50 mM, and wherein said polypeptide is expressed in the vertebrate in an amount sufficient to be detectable.

359. (previously added) The method of claim 358, wherein the auxiliary agent is a poloxamer.

360. (previously added) The method of claim 358, wherein the auxiliary agent is a reverse poloxamer.

361. (currently amended) The method of claim 359, wherein the poloxamer has a molecular weight from 1000 grams per mole to greater than 16000 grams per mole.

362. (currently amended) The method of claim 359, wherein the poloxamer has an approximate hydrophobe molecular weight from 900 grams per mole to 3600 grams per mole and an approximate hydrophile weight percentage of 10% to 80%.

363. (currently amended) The method of claim 360, wherein the reverse poloxamer has an approximate hydrophobe molecular weight of 1000 grams per mole to 3100 grams per mole and an approximate hydrophile weight percentage of 10% to 80%.

364. (currently amended) The method of claim 363, wherein the reverse poloxamer has an approximate hydrophobe molecular weight of about 2500 grams per mole and an approximate hydrophile weight percentage of about 20%.

365. (currently amended) The method of claim 359, wherein the poloxamer is selected from the group consisting of a poloxamer having an approximate hydrophobe molecular weight of 1800 grams per mole and an approximate hydrophile weight percentage of 80%; a poloxamer having an approximate hydrophobe molecular weight of 2100 grams per mole and an approximate hydrophile weight percentage of 70%; a poloxamer having an approximate hydrophobe molecular weight of 3000 grams per mole and an approximate hydrophile weight percentage of 80%; a poloxamer having an approximate hydrophobe molecular weight of 2400 grams per mole and an approximate hydrophile weight percentage of 40%; a poloxamer having an approximate hydrophobe molecular weight of 1200 grams per mole and an approximate hydrophile weight percentage of 40%; a poloxamer having an approximate hydrophobe molecular weight of 1800 grams per mole and an approximate hydrophile weight percentage of 20%; and a poloxamer having an approximate hydrophobe molecular weight of 1800 grams per mole and an approximate hydrophile weight percentage of 40%.

366. (currently amended) The method of claim 360, wherein the reverse poloxamer is selected from the group consisting of a reverse poloxamer having an approximate hydrophobe molecular weight of 1700 grams per mole and an approximate hydrophile weight percentage of 40%; a reverse poloxamer having an approximate hydrophobe molecular weight of 2500 grams per mole and an approximate hydrophile weight percentage of 40%; and a reverse poloxamer having an approximate hydrophobe molecular weight of 2500 grams per mole and an approximate hydrophile weight percentage of 20%.

367. (currently amended) The method of claim 366, wherein the reverse poloxamer has an approximate hydrophobe molecular weight of 2500 grams per mole and an approximate hydrophile weight percentage of 20%.

368. (currently amended) The method of claim 358, wherein the auxiliary agent is selected from the group consisting of about 0.1% (w/v) to about 6.0% (w/v) of a poloxamer having an approximate hydrophobe molecular weight of 1800 grams per mole and an approximate hydrophile weight percentage of 80%; about 0.001% (w/v) to about 2.0% (w/v) of a poloxamer having an approximate hydrophobe molecular weight of 2100 grams per mole and an approximate hydrophile weight percentage of 70%; and about 0.01% (w/v) to about 1% (w/v) of a poloxamer having an approximate hydrophobe molecular weight of 1800 grams per mole and an approximate hydrophile weight percentage of 50%.

369. (currently amended) The method of claim 360, wherein the reverse poloxamer has an approximate hydrophobe molecular weight of 2500 grams per mole and an approximate hydrophile weight percentage of 20% and is present in the composition in a concentration of about 0.001% (w/v) to about 1.0% (w/v).

370. (currently amended) The method of claim 358, wherein the auxiliary agent is selected from the group consisting of about 0.5% to about 4.0% (w/v) of a poloxamer having an approximate hydrophobe molecular weight of 1800 grams per mole and an approximate hydrophile weight percentage of 80%; about 0.1% (w/v) to about 1.7% (w/v) of

a poloxamer having an approximate hydrophobe molecular weight of 2100 grams per mole and an approximate hydrophile weight percentage of 70%; and about 0.01% (w/v) to about 0.5% (w/v) of a poloxamer having an approximate hydrophobe molecular weight of 1800 grams per mole and an approximate hydrophile weight percentage of 40%.

371. (currently amended) The method of claim 358, wherein the auxiliary agent is selected from the group consisting of 4%(w/v) of a poloxamer having an approximate hydrophobe molecular weight of 1800 grams per mole and an approximate hydrophile weight percentage of 80%; 1.0% (w/v) of a poloxamer having an approximate hydrophobe molecular weight of 2100 grams per mole and an approximate hydrophile weight percentage of 70%; and 0.5% (w/v) of a poloxamer having an approximate hydrophobe molecular weight of 1800 grams per mole and an approximate hydrophile weight percentage of 50%.

372. (currently amended) The method of claim 359, wherein the poloxamer is selected from the group consisting of a poloxamer having an approximate hydrophobe molecular weight of 1800 grams per mole and an approximate hydrophile weight percentage of 50%; a poloxamer having an approximate hydrophobe molecular weight of 3000 grams per mole and an approximate hydrophile weight percentage of 30%; a poloxamer having an approximate hydrophobe molecular weight of 3000 grams per mole and an approximate hydrophile weight percentage of 40%; a poloxamer having an approximate hydrophobe molecular weight of 3000 grams per mole and an approximate hydrophile weight percentage of 50%; a poloxamer having an approximate hydrophobe molecular weight of 3600 grams per mole and an approximate hydrophile weight percentage of 30%; a poloxamer having an

approximate hydrophobe molecular weight of 900 grams per mole and an approximate hydrophile weight percentage of 10%; a poloxamer having an approximate hydrophobe molecular weight of 1200 grams per mole and an approximate hydrophile weight percentage of 30%; a poloxamer having an approximate hydrophobe molecular weight of 1800 grams per mole and an approximate hydrophile weight percentage of 10%; a poloxamer having an approximate hydrophobe molecular weight of 2400 grams per mole and an approximate hydrophile weight percentage of 10%; a poloxamer having an approximate hydrophobe molecular weight of 2700 grams per mole and an approximate hydrophile weight percentage of 20%; a poloxamer having an approximate hydrophobe molecular weight of 3000 grams per mole and an approximate hydrophile weight percentage of 10%; and a poloxamer having an approximate hydrophobe molecular weight of 3600 grams per mole and an approximate hydrophile weight percentage of 10%.

373. (currently amended) The method of claim 358, wherein the auxiliary agent is selected from the group consisting of about 0.01% (w/v) to about 1.0% (w/v) of a poloxamer having an approximate hydrophobe molecular weight of 3000 grams per mole and an approximate hydrophile weight percentage of 80%; about 0.01% (w/v) to about 1.0% (w/v) of a poloxamer having an approximate hydrophobe molecular weight of 3000 grams per mole and an approximate hydrophile weight percentage of 30%; about 0.0005% (w/v) to about 1.0% (w/v) of a poloxamer having an approximate hydrophobe molecular weight of 1200 grams per mole and an approximate hydrophile weight percentage of 40%; about 0.01% (w/v) to about 1.0% (w/v) of a poloxamer having an approximate hydrophobe molecular weight of 1800 grams per mole and an approximate hydrophile weight percentage

of 40%; about 0.002% (w/v) to about 1.0% (w/v) of a reverse poloxamer having an approximate hydrophobe molecular weight of 1700 grams per mole and an approximate hydrophile weight percentage of 40%; about 0.002% (w/v) to about 1.0% (w/v) of a reverse poloxamer having an approximate hydrophobe molecular weight of 2500 grams per mole and an approximate hydrophile weight percentage of 40%; and about 0.001% (w/v) to about 1.0% (w/v) of a reverse poloxamer having an approximate hydrophobe molecular weight of 2500 grams per mole and an approximate hydrophile weight percentage of 20%.

374. (currently amended) The method of claim 358, wherein the auxiliary agent is selected from the group consisting of about 0.05% (w/v) to about 0.5% (w/v) of a poloxamer having an approximate hydrophobe molecular weight of 3000 grams per mole and an approximate hydrophile weight percentage of 80%; about 0.1% (w/v) to about 1% (w/v) of a poloxamer having an approximate hydrophobe molecular weight of 1800 grams per mole and an approximate hydrophile weight percentage of 50%; ~~about 0.05% (w/v) to about 0.10% (w/v) of a poloxamer having an approximate hydrophobe molecular weight of 3000 grams per mole and an approximate hydrophile weight percentage of 30%;~~ about 0.001% (w/v) to about 0.10% (w/v) of a poloxamer having an approximate hydrophobe molecular weight of 1200 grams per mole and an approximate hydrophile weight percentage of 40%; about 0.01% (w/v) to about 0.10% (w/v) of a reverse poloxamer having an approximate hydrophobe molecular weight of 1700 grams per mole and an approximate hydrophile weight percentage of 40%; about 0.01% (w/v) to about 0.10% (w/v) of a reverse poloxamer having an approximate hydrophobe molecular weight of 2500 grams per mole and an approximate hydrophile weight percentage of 40%; and about 0.001% (w/v) to about

0.1% (w/v) of a reverse poloxamer having an approximate hydrophobe molecular weight of 2500 grams per mole and an approximate hydrophile weight percentage of 20%.

375. (currently amended) The method of claim 374, wherein the auxiliary agent is about 0.001% (w/v) to about 0.1% (w/v) of a reverse poloxamer having an approximate hydrophobe molecular weight of 2500 grams per mole and an approximate hydrophile weight percentage of 20%.

376. (currently amended) The method of claim 358, wherein the auxiliary agent is selected from the group consisting of 0.1% (w/v) of a poloxamer having an approximate hydrophobe molecular weight of 3000 grams per mole and an approximate hydrophile weight percentage of 80%; 0.05% (w/v) of a poloxamer having an approximate hydrophobe molecular weight of 3000 grams per mole and an approximate hydrophile weight percentage of 30%; 0.001% (w/v) of a poloxamer having an approximate hydrophobe molecular weight of 1200 grams per mole and an approximate hydrophile weight percentage of 40%; about 0.01% (w/v) to about 0.1% (w/v) of a poloxamer having an approximate hydrophobe molecular weight of 1800 grams per mole and an approximate hydrophile weight percentage of 40%; 0.10% (w/v) of a reverse poloxamer having an approximate hydrophobe molecular weight of 1700 grams per mole and an approximate hydrophile weight percentage of 40%; 0.01% (w/v) of a reverse poloxamer having an approximate hydrophobe molecular weight of 2500 grams per mole and an approximate hydrophile weight percentage of 40%; and 0.01% (w/v) of a reverse poloxamer having an approximate hydrophobe molecular weight of 2500 grams per mole and an approximate hydrophile weight percentage of 20%.

377. (currently amended) The method of claim 376, wherein the auxiliary agent is 0.01% (w/v) of a reverse poloxamer having an approximate hydrophobe molecular weight of 2500 grams per mole and an approximate hydrophile weight percentage of 20%.

378. (currently amended) The method of claim 358, wherein the auxiliary agent is selected from the group consisting of about 0.001% (w/v) to about 0.1% (w/v) of a poloxamer having an approximate hydrophobe molecular weight of 900 grams per mole and an approximate hydrophile weight percentage of 10%; about 0.001% (w/v) to about 0.1% (w/v) of a poloxamer having an approximate hydrophobe molecular weight of 1800 grams per mole and an approximate hydrophile weight percentage of 10%; and about 0.001 % (w/v) to about 1.0% (w/v) of a poloxamer having an approximate hydrophobe molecular weight of 2700 grams per mole and an approximate hydrophile weight percentage of 20%.

379. (currently amended) The method of claim 358, wherein the auxiliary agent is selected from the group consisting of 0.05% (w/v) of a poloxamer having an approximate hydrophobe molecular weight of 900 grams per mole and an approximate hydrophile weight percentage of 10%; 0.01% (w/v) of a poloxamer having an approximate hydrophobe molecular weight of 1800 grams per mole and an approximate hydrophile weight percentage of 10%; and 0.05% (w/v) of a poloxamer having an approximate hydrophobe molecular weight of 2700 grams per mole and an approximate hydrophile weight percentage of 20%.

380. (previously added) The method of claim 358, wherein M is selected from the group consisting of sodium and potassium, and wherein X is selected from the group consisting of phosphate, acetate, and bicarbonate.

381. (previously added) The method of claim 380, wherein said salt is sodium phosphate or potassium phosphate.

382. (previously added) The method of claim 358, wherein said salt is dissolved in said aqueous solution at a concentration ranging from about 100 mM to 200 mM.

383. (previously added) The method of claim 358, wherein said salt is dissolved in said aqueous solution at a concentration of about 150 mM.

384. (previously added) The method of claim 358, wherein said aqueous solution contains chloride ion at a molar concentration ranging from 0 mM to about 30 mM.

385. (previously added) The method of claim 358, wherein said aqueous solution contains chloride ion at a molar concentration ranging from 0 mM to about 15 mM.

386. (previously added) The method of claim 358, wherein said aqueous solution contains chloride ion at a molar concentration ranging from 0 mM to about 5 mM.

387. (previously added) The method of claim 358, wherein said polynucleotide is DNA operably associated with a promoter.

388. (previously added) The method of claim 387, wherein said polynucleotide is contained on a plasmid.

389. (previously added) The method of claim 358, wherein said polynucleotide is RNA.

390. (previously added) The method of claim 389, wherein said polynucleotide is contained in messenger RNA.

391. (previously added) The method of claim 358, wherein said polypeptide is selected from the group consisting of a therapeutic polypeptide, an antigenic polypeptide, an immunogenic polypeptide, an immunomodulatory polypeptide, and a functional self polypeptide.

392. (currently amended) The method of claim 391, wherein said therapeutic polypeptide is selected from the group consisting of granulocyte macrophage colony stimulating factor, granulocyte colony stimulating factor, macrophage colony stimulating factor colony stimulating factor, interleukin 2, interleukin-3, interleukin 4, interleukin 5, interleukin 6, interleukin 7, interleukin 8, interleukin 10, interleukin 12, interleukin 15, interleukin 18, interferon alpha, interferon beta, interferon gamma, interferon omega,

interferon tau, interferon gamma inducing factor I, transforming growth factor beta, RANTES, macrophage inflammatory proteins, Leishmania elongation initiating factor, platelet derived growth factor, tumor necrosis factor, epidermal growth factor, vascular epithelial growth factor, fibroblast growth factor, nerve growth factor, brain derived neurotrophic factor, neurotrophin-2, neurotrophin-3, neurotrophin-4, neurotrophin-5, glial cell line-derived neurotrophic factor, ciliary neurotrophic factor, erythropoietin, insulin, and therapeutically active fragments ~~, analogs, or derivatives~~ thereof.

393. (currently amended) The method of claim 391, wherein said immunogenic polypeptide is selected from the group consisting of a bacterial polypeptide, a viral polypeptide, a fungal polypeptide, a parasite polypeptide, an allergen, a tumor specific polypeptide, and immunogenic fragments ~~, analogs, or derivatives~~ thereof.

394. (currently amended) The method of claim 391, wherein said immunomodulatory polypeptide is selected from the group consisting of a cytokine, a chemokine, and immunomodulatory fragments ~~, analogs, or derivatives~~ thereof.

395. (currently amended) The method of claim 391, wherein said functional self polypeptide is selected from the group consisting of insulin, dystrophin, cystic fibrosis transmembrane conductance regulator, granulocyte macrophage colony stimulating factor, granulocyte colony stimulating factor, macrophage colony stimulating factor colony stimulating factor, interleukin 2, interleukin-3, interleukin 4, interleukin 5, interleukin 6, interleukin 7, interleukin 8, interleukin 10, interleukin 12, interleukin 15, interleukin 18,

interferon alpha, interferon beta, interferon gamma, interferon omega, interferon tau, interferon gamma inducing factor I, transforming growth factor beta, RANTES, macrophage inflammatory proteins, platelet derived growth factor, tumor necrosis factor, epidermal growth factor, vascular epithelial growth factor, fibroblast growth factor, nerve growth factor, brain derived neurotrophic factor, neurotrophin-2, neurotrophin-3, neurotrophin-4, neurotrophin-5, glial cell line-derived neurotrophic factor, ciliary neurotrophic factor, erythropoietin, and therapeutically active fragments ~~, analogs,and derivatives~~ thereof.

396. (previously added) The method of claim 358, further comprising a transfection facilitating agent selected from the group consisting of cationic lipids, calcium phosphate, alum, gold, tungsten, or other metal particles, transfection facilitating peptides, transfection facilitating proteins, and transfection facilitating polymers.

397. (previously added) The method of claim 396, wherein said transfection facilitating agent is a cationic lipid.

398. (previously added) The method of claim 358, wherein said vertebrate is a mammal.

399. (previously added) The method of claim 398, wherein said mammal is a human.

400. (previously added) The method of claim 358, wherein said tissue is selected from the group consisting of muscle, skin, brain tissue, lung tissue, liver tissue, spleen tissue, bone marrow tissue, thymus tissue, heart tissue, lymph tissue, blood tissue, bone tissue, connective tissue, mucosal tissue, pancreas tissue, kidney tissue, gall bladder tissue, intestinal tissue, testicular tissue, ovarian tissue, uterine tissue, vaginal tissue, rectal tissue, nervous system tissue, eye tissue, glandular tissue, and tongue tissue.

401. (currently amended) The method of claim 358, wherein said cavity is selected from the group consisting of the lungs, the mouth, the nasal cavity, the stomach, the peritoneal cavity, the intestine, a heart chamber, veins, arteries, capillaries, lymphatic cavities, the uterine cavity, the vaginal cavity, the rectal cavity, joint cavities, ventricles in brain, spinal canal ~~in spinal cord~~, and the ocular cavities.

402. (previously added) The method of claim 358, wherein said cavity comprises a mucosal surface.

403. (previously added) The method of claim 402 wherein said mucosal surface is lung tissue.

404. (previously added) The method of claim 400, wherein said tissue is muscle.

405. (previously added) The method of claim 404, wherein said tissue is skeletal muscle, smooth muscle, or myocardium.

406. (previously added) The method of claim 358, wherein said administration is by a route selected from the group consisting of intramuscular, intravenous, intratracheal, intranasal, transdermal, interdermal, subcutaneous, intraocular, vaginal, rectal, intraperitoneal, intraintestinal and inhalation.

407. (previously added) The method of claim 358, wherein said administration route is intravenous.

408. (previously added) The method of claim 358, wherein said administration route is intramuscular.

409. (previously added) The method of claim 408, wherein said administration is by intramuscular injection.

410. (previously added) The method of claim 358, wherein said administration is mediated by a catheter.

411. (currently amended) A composition for delivering a polypeptide into a vertebrate, comprising ~~administering into a tissue or cavity of said vertebrate a composition comprising~~ :

(a) about 1 ng to about 30 mg of a polynucleotide in aqueous solution ~~which operably encodes~~ , wherein the polynucleotide expresses a polypeptide upon delivery to vertebrate cells *in vivo*;

(b) a salt M-X dissolved in said aqueous solution at a molar concentration ranging from about 50 mM to about 250 mM, and reaction, association, and dissociation products thereof, wherein M is a cation selected from the group consisting of sodium and potassium, wherein X is an anion selected from the group consisting of phosphate, acetate, sulfate, and pyruvate; and

(c) an auxiliary agent selected from the group consisting of a poloxamer and a reverse poloxamer;

wherein said aqueous solution contains chloride ion at a molar concentration ranging from 0 mM to about 50 mM, and wherein said polypeptide is expressed in the vertebrate in an amount sufficient to be detectable.

412. (previously added) The composition of claim 411, wherein said salt is dissolved in said aqueous solution at a concentration ranging from about 100 mM to 200 mM.

413. (previously added) The composition of claim 411, wherein said salt is dissolved in said aqueous solution at a concentration of about 150 mM.

414. (previously added) The composition of claim 411, wherein X of said salt is phosphate.

415. (previously added) The composition of claim 411, wherein said aqueous solution contains chloride ion at a molar concentration ranging from 0 mM to about 30 mM.

416. (previously added) The composition of claim 411, wherein said aqueous solution contains chloride ion at a molar concentration ranging from 0 mM to about 15 mM.

417. (previously added) The composition of claim 411, wherein said aqueous solution contains chloride ion at a molar concentration ranging from 0 mM to about 5 mM.